



HEPATITIS C AGENTS PA SUMMARY

Preferred	Non-Preferred
Direct Inhibitors Harvoni (ledipasvir and sofosbuvir)* Sovaldi (sofosbuvir)*	Olysio (simeprevir)* Viekira Pak (ombitasvir, paritaprevir and ritonavir; dasabuvir)*
Ribavirin Ribavirin/Ribasphere generic 200 mg Rebetol oral solution (ribavirin)	Moderiba (ribavirin)* RibaPak (ribavirin)* Ribasphere 400, 600 mg (ribavirin)*
Pegylated Interferons Pegasys (peginterferon alfa-2a) PegIntron (peginterferon alfa-2b)	
Interferons Intron-A (interferon alfa-2b)	

*Requires prior authorization

LENGTH OF AUTHORIZATION:

❖ For Harvoni, the length of authorization is summarized in the table below.

Patient Population	Duration
Treatment-naïve without cirrhosis who have pre-treatment HCV RNA < 6 million IU/mL	8 weeks
Treatment-naïve without cirrhosis who have pre-treatment HCV RNA \geq 6 million IU/mL	12 weeks
Treatment-naïve with cirrhosis	12 weeks
Treatment-experienced without cirrhosis	12 weeks
Treatment-experienced with cirrhosis	24 weeks

❖ For Olysio, the length of authorization is 12 weeks.

❖ For Sovaldi, the length of authorization is summarized in the table below.

Patient Population	Treatment	Duration
Genotype 1	Sovaldi + peginterferon + ribavirin	12 weeks
Genotype 1 interferon ineligible	Sovaldi + ribavirin	24 weeks
Genotype 2	Sovaldi + ribavirin	12 weeks
Genotype 3	Sovaldi + ribavirin	24 weeks
Genotype 4	Sovaldi + peginterferon + ribavirin	12 weeks
Hepatocellular carcinoma awaiting liver transplantation	Sovaldi + ribavirin	Up to 48 weeks or until liver transplantation, whichever occurs first

❖ For Viekira Pak, the length of authorization is summarized in the table below.

Patient Population	Treatment	Duration
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Genotype 1a without cirrhosis	Viekira Pak + ribavirin	12 weeks
Genotype 1a with cirrhosis and treatment-naïve or null responder to prior peginterferon therapy or relapsed after prior peginterferon therapy	Viekira Pak + ribavirin	24 weeks
Genotype 1a with cirrhosis and partial response to prior peginterferon therapy	Viekira Pak + ribavirin	12 weeks
Genotype 1b without cirrhosis	Viekira Pak	12 weeks
Genotype 1b with cirrhosis	Viekira Pak + ribavirin	12 weeks
Genotype 1 with liver transplant	Viekira Pak + ribavirin	24 weeks

PA CRITERIA:

Harvoni

- ❖ Members must be 18 years of age or older with a diagnosis of genotype 1 (1a or 1b) chronic hepatitis C virus infection (CHC, HCV).
- ❖ Members who abuse alcohol or intravenous drugs must be enrolled in a substance abuse program.

Moderiba, RibaPak, and Ribasphere 400mg, 600mg

- ❖ Physician must submit a written letter of medical necessity stating the reason(s) the preferred product, generic ribavirin tablets or capsules, is not appropriate for the member.

Olysio

- ❖ Members must be 18 years of age or older with a diagnosis of genotype 1 (1a or 1b) chronic hepatitis C virus infection (CHC, HCV) with compensated liver disease.
- ❖ For use with Sovaldi, members must not be able to take or tolerate Harvoni and Viekira Pak.
- ❖ For use with peginterferon and ribavirin, members must not be able to take or tolerate Sovaldi. In addition, members infected with genotype 1a must not contain the NS3Q80K polymorphism.
- ❖ Members who have previously failed therapy with a protease inhibitor due to lack of response are not eligible for Olysio.
- ❖ Members who abuse alcohol or intravenous drugs must be enrolled in a substance abuse program.

Sovaldi

- ❖ Members must be 18 years of age or older with a diagnosis of chronic hepatitis C infection (CHC) with the following genotypes: 1 (1a or 1b), 2, 3, or 4, or have hepatocellular carcinoma awaiting liver transplantation.
- ❖ Members with hepatocellular carcinoma awaiting liver transplantation must use in combination with ribavirin.
- ❖ Members with genotype 1 (1a or 1b) must use Sovaldi in combination with Olysio, with peginterferon alfa and ribavirin or with ribavirin alone. For use with Olysio, members must not be able to take or tolerate Harvoni and Viekira Pak.
- ❖ Members with genotype 2, must use Sovaldi in combination with ribavirin.
- ❖ Members with genotype 3 must use Sovaldi in combination with ribavirin.
- ❖ Members with genotype 4 must use Sovaldi in combination with peginterferon alfa and ribavirin.



- ❖ Members who abuse alcohol or intravenous drugs must be enrolled in a substance abuse program.

Viekira Pak

- ❖ Members must be 18 years of age or older with a diagnosis of genotype 1 (1a or 1b) chronic hepatitis C virus infection (CHC, HCV) with compensated liver disease.
- ❖ Members must not be able to take or tolerate Harvoni.
- ❖ Members with genotype 1b without cirrhosis may use Viekira Pak without ribavirin; all other members must use Viekira Pak with ribavirin.
- ❖ Members who are also liver transplant recipients must have normal liver function and can have up to mild fibrosis.
- ❖ Members who abuse alcohol or intravenous drugs must be enrolled in a substance abuse program

EXCEPTIONS:

- ❖ Exceptions to these conditions of coverage are considered through the prior authorization process.
- ❖ The Prior Authorization process may be initiated by calling **Catamaran at 1-866-525-5827.**

PA and APPEAL PROCESS:

- ❖ For online access to the PA process, please go to www.dch.georgia.gov/prior-authorization-process-and-criteria and click on Prior Authorization (PA) Request Process Guide.

QUANTITY LEVEL LIMITATIONS:

- ❖ For online access to the current Quantity Level Limits (QLL), please go to www.mmis.georgia.gov/portal, highlight Provider Information and click on Provider Manuals. Scroll to the page with Pharmacy Services and select that manual.